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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/422,999	10/22/1999	HIROAKI KAWASAKI	MIT-103	6219
21323	7590	06/07/2004	EXAMINER	
TESTA, HURWITZ & THIBEAULT, LLP HIGH STREET TOWER 125 HIGH STREET BOSTON, MA 02110			MURPHY, JOSEPH F	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 06/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/422,999

**Applicant(s)**

KAWASAKI ET AL.

**Examiner**

Joseph F Murphy

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 40-47, 50-54, 62 and 131-134 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40-47 is/are allowed.
- 6) ☒ Claim(s) 50-54 and 131-134 is/are rejected.
- 7) ☒ Claim(s) 62 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>03102004</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Formal Matters***

Claims 40-47, 50-54, 62, 131-134 are pending and under consideration.

***Response to Amendment***

Applicant's arguments filed 3/18/2004 have been fully considered but they are persuasive in part.

The rejection of claims 40-47, 51, 53-54, 62, 133-134 under 35 U.S.C. 112, first paragraph, because the specification, which is enabling for a full length nucleic acid of SEQ ID NO: 17, does not reasonably provide enablement for a nucleic acid which is complementary to SEQ ID NO: 17 has been obviated by Applicant's amendment, and is thus withdrawn.

Remaining issues and new issues are set forth below.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 50-54, 131-134 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 50, 52, 131, 132 as written read on embryonic stem cells, gametes and germ line cells transfected with a nucleic acid. As it would be possible that these cells could be used in a process of in vitro fertilization and implantation, they read on a transgenic human, which is not patentable subject matter.

Applicant has amended the claims to recite that the host cells are in culture and argues that this obviates the rejection. However, claims 50 and 131 are directed to descendants of the

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transformed cells, and are directed to non-statutory subject matter because the claims read on a product of nature. Claim 50 and 131 are directed to descendants of host cells that comprise the vector, but there is no requirement that the descendants actually comprise the vector.

Descendants of a host cell comprising, e.g. a plasmid vector, can lose the plasmid, and even in stably transfected cells, wherein the gene is incorporated into the genome of the cells, the recombinant gene can be lost over time and through a number of passages. Since the claims do not require that the descendant cells retain the vector, they read on a product of nature and are thus non-statutory.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50, 52, 131, 132 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic mouse comprising a nucleotide sequence set forth in SEQ ID NO: 17, does not reasonably provide enablement for a transgenic animal other than a mouse comprising a nucleotide sequence set forth in SEQ ID NO: 17, for reasons of record set forth in the Office Action of 12/18/2003. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection of record set forth that the rejection under 35 U.S.C. 112, first paragraph is directed to claims 50, 52, 131, 132 as they read on the use embryonic stem cells for the creation of transgenic non-human animals:

With regard to the claim breadth directed to transgenic non-human animals, the specification fails to teach the production of any transgenic non-human animal comprising a nucleic acid other than a transgenic mouse comprising a nucleotide sequence set forth in SEQ ID NO: 17. It is well known in the art that the production of transgenic animals other than mice is undeveloped. This is because ES cell technology is generally limited to the mouse system, at present, and that only “putative” ES cells exist for other species. See Moreadith et al. at page 214, Summary. Seamark (Reproductive Fertility and Development, 1994) supports this observation by reporting that totipotency for ES cell technology in many livestock species has not been demonstrated (page 6, Abstract). Likewise, Mullins et al. (Journal of Clinical Investigation, 1996) state that “although to date chimeric animals have been generated from several species including the pig, in no species other than the mouse has germline transmission of an ES cell been successfully demonstrated.” (page S38, column 1, first paragraph). As the claims encompass transgenic non-human animals, which must be generated by the introduction of a transgene into an ES cell, the state of the art supports that only mouse ES cells were available for use for production of transgenic mice. Given the unpredictable state of the art it would have required undue experimentation for the skilled artisan to create transgenic non-human animals of species other than the mouse. No arguments were directed to this aspect of the rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 50-54, 131-134 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,959,313 (Taketo).

The '313 patent discloses that host cells may be selected from the group consisting of Escherichia coli, host animal cells, NIH3T3 fibroblasts, mouse embryonic stem cells (ES cells or EK cells), embryonal carcinoma (EC) cells, primordial germ (PG) cells, and early embryo cells. The claims are anticipated because the claims as written are directed to descendants of the transformed cells, and further given that descendants of a host cell comprising a plasmid vector, can lose the plasmid, and the transgene in stably transfected cells, wherein the gene is incorporated into the genome of the cells, can be lost over time and through a number of passages. Since the claims do not require that the descendant cells retain the vector, the host cells as disclosed in the '313 anticipate the claims as written.

***Conclusion***

Claims 50-54, 131-134 are rejected.

Claim 62 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 40-47 are allowable.

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*Advisory Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to be 'J. F. Murphy', with a long, sweeping horizontal stroke extending to the right.

Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
May 24, 2004